



ATTORNEY DOCKET NO.: 2002834-0046 (Peanut Allergens CIP 10)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Bannon et al. Examiner: Huynh, P.  
Serial No.: 09/494,096 Art Unit: 1644  
Filing Date: January 28, 2000  
Title: METHODS AND REAGENTS FOR DECREASING CLINICAL  
REACTION TO ALLERGY

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or  
☒ A *supplemental* Information Disclosure Statement.

Certificate of Mailing	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
<u>1-29-04</u>	<u>Sandra Saccoccia</u>
Date	Signature
<u>Sandra Saccoccia</u>	
Typed or Printed Name of person signing certificate	

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☐ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☐ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
  - ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

### Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☐ A copy of each cited reference not indicated with an asterisk is included;
- ☒ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status
<b>09/141,220</b>	<b>August 27, 1998</b>	<b>Pending</b>

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise explanation:
- ☐ Includes one or more translations of a non-English citation.

## Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

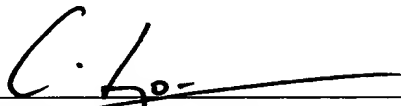
The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

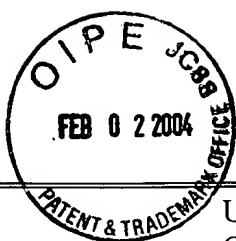
  
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<b>PTO-1449</b> <b>(REV. 8-83)</b>  <b>SUPPLEMENTAL</b> <b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	U.S. Department of Commerce Patent and Trademark Office	<b>ATTY. DOCKET:</b> <b>2002834-0046</b>	<b>IN RE</b> <b>APPLICATION NO.:</b> <b>09/494,096</b>
		<b>APPLICANT:</b> Bannon et al.	
		<b>FILING DATE:</b> January 28, 2000	<b>GROUP:</b> 1644

#### U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	*5,888,799	Curtiss III	March 30, 1999		
	*5,830,463	Duke, et al.	November 3, 1998		
	*5,389,368	Gurtiss III	February 14, 1995		

#### U.S. PATENT APPLICATIONS

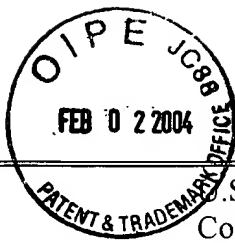
Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	*CA 2 158 047	Canada	15 September 1994		
	*CA 2 157 596	Canada	29 September 1994		
	*JP 07095887	Japan	11 April 1995		
	*JP 06253851	Japan	13 September 1994		
	*WO 00/54803	PCT	21 September 2000		
	*WO 99/25387	PCT	27 May 1999		
	*WO 94/20614	PCT	15 September 1994		

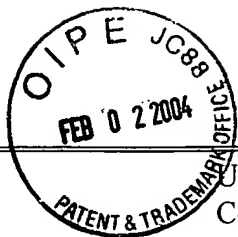
#### OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	*Burks, et al., "Epitope Specificity of the Major Peanut Allergen, Ara h II", <i>J. Allergy Clin. Immunol.</i> <b>95</b> : 607-611, 1995.
	*Gayler, et al., "Biosynthesis, cDNA and Amino Acid Sequences of a Precursor of Conglutin $\delta$ , A Sulphur-Rich Protein from <i>Lupinus Angustifolius</i> ", <i>Plant Molecular Biology</i> , <b>15</b> : 879-893, 1990.



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		*Ichikawa, et al., "Solution Structure of Der f 2, the Major Mite Allergen for Atopic Disease", <i>J. Mol. Chem.</i> , <b>273</b> : 356-360, 1998.					
		*Medaglini, et al., "Mucosal and Systemic Immune Responses to a Recombinant Protein Expressed on the Surface of the Oral Commensal Bacterium <i>Streptococcus Gordonii</i> After Oral Colonization", <i>Proceedings of the National Academy of Sciences of the United States of America</i> , <b>92</b> (15): 6868-6872, 1995.					
		*Nishiyama, et al., "Analysis of the IgE-epitope of Der f 2, a Major Mite Allergen, by in vitro Mutagenesis", <i>Mol. Immunol.</i> , <b>32</b> : 1021-1029, 1995.					
		*Nishiyama, et al., "Effects of Amino Acid Variations in Recombinant Der f II on its Human IgE and Mouse IgG Recognition", <i>Int. Arch. Allergy Immunol.</i> , <b>105</b> : 62-69, 1994.					
		*Takai, et al., "Effect of Proline Mutations in the Major House Dust Mite Allergen Der f 2 on IgE-binding and Histamine-releasing Activity", <i>Eur. J. Biochem.</i> , <b>267</b> : 6650-6656, 2000.					
		*Takai, et al., "Non-anaphylactic Combination of Partially Deleted Fragments of the Major House Dust Mite Allergen Der f 2 for Allergen-specific Immunotherapy", <i>Mol. Immunol.</i> , <b>36</b> : 1055-1065, 1999.					
		*Takai, et al., "Determination of the N- and C-terminal Sequences to Bind Human IgE of the Major House Dust Mite Allergen Der f 2 and Epitope Mapping for Monoclonal Antibodies", <i>Mol. Immunol.</i> , <b>34</b> : 255-261, 1997.					
		*Takai, et al., "Engineering of the Major House Dust Mite Allergen Der f 2 for Allergen-specific Immunotherapy", <i>Nat. Biotechnol.</i> , <b>15</b> : 754-758, 1997.					
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		*EMBL Accession No. L77197 (March 1996)					
EXAMINER				DATE CONSIDERED			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							





<b>PTO-1449</b> <b>(REV. 8-83)</b>  <b>SUPPLEMENTAL</b> <b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	U.S. Department of Commerce Patent and Trademark Office	<b>ATTY. DOCKET:</b> <b>2002834-0046</b>	<b>IN RE</b> <b>APPLICATION NO.:</b> <b>09/494,096</b>
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<b>U.S. PATENT DOCUMENTS</b>
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Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	*6,218,371	Krieg et al.	April 17, 2001	514	44
	*5,061,790	Elting et al.	October 29, 1991	530	402
	*4,959,314	Mark et al.	September 25, 1990	435	69.1
	*4,849,404	Iwai et al.	July 18, 1989	514	2
	*4,658,022	Knowles et al.	April 14, 1987	530	402

<b>U.S. PATENT APPLICATIONS</b>
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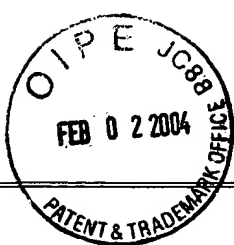
Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

<b>FOREIGN PATENT DOCUMENTS</b>
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Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No

<b>OTHER DOCUMENTS</b>
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Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	*Del Val, et al., "Thioredoxin Treatment Increases Digestibility and Lowers Allergenicity of Milk", <i>J. Allergy Clin. Immunol.</i> 103(4): 690-697, 1999.
	*Hoyne, et al., "Peptide-Mediated Regulation of the Allergic Immune Response", <i>Immunol. Cell Biol.</i> 74(2): 180-186, 1996.
	*Vailes, et al., "Fine Specificity of B-Cell Epitopes on Felis Domesticus Allergen I (Fel d I): Effect of Reduction and Alkylation or Deglycosylation of Fel d I Structure and Antibody Binding", <i>J. Allergy Clin. Immunol.</i> 93(1): 22-33, 1994.
	*Burns, et al., "Selective Reduction of Disulfides by Tris (2-Carboxyethyl) Phosphine", <i>J. Org. Chem.</i> 56(8): 2648-2650, 1991.
	*Gray, et al., "Echistatin Disulfide Bridges: Selective Reduction and Linkage Assignment", <i>The Protein Society</i> , 1749-1755, 1993.



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	*Gray, et al., "Disulfide Structures of Highly Bridged Peptides: A New Strategy for Analysis", <i>The Protein Society</i> , 1732-1748, 1993.			
	*Herbert, et al., "Reduction and Alkylation of Proteins in Preparation of Two-Dimensional Map Analysis: Why, When, and How?" <i>Electrophoresis</i> , 22: 2046-2057, 2001.			
	*Nakamura, et al., "Mass Spectrometric-Based Revision of the Structure of a Cysteine-Rich Peptide Toxin with Gamma-Carboxyglutamic Acid, TxVIIA, from the Sea Snail, Conus Textile", <i>Protein Science</i> , 5(3): 524-530, 1996.			
	*Olsson, et al., "Contribution of Disulphide Bonds to Antigenicity of Lep d 2, the Major Allergen of the Dust Mite <i>Lepidoglyphus Destructor</i> ", <i>Molecular Immunology</i> , 35: 1017-1023, 1998.			
	*Smith, et al., "Localization of Antigenic Sites on Der p 2 Using Oligonucleotide-Directed Mutagenesis Targeted to Predicted Surface Residues", <i>Clinical and Experimental Allergy</i> , 27: 593-599, 1997.			
	*Smith, et al., "Recombinant Allergens for Immunotherapy: A Der p 2 Variant with Reduced IgE Reactivity Retains T-Cell Epitopes", <i>J. Allergy Clin. Immunol.</i> 101(3): 423-425, 1998.			
	*Smith, et al., "Reduction in IgE Binding to Allergen Variants Generated by Site-Directed Mutagenesis: Contribution of Disulfide Bonds to the Antigenic Structure of the Major House Dust Mite Allergen Der p 2", <i>Molecular Immunology</i> , 33(4/5): 399-405, 1996.			
	*Watson, et al., "Trapping and Identification of Folding Intermediates of Disulfide Bond-Forming Proteins Based on Cyanylation, Cleavage, and Analysis by Mass Spectrometry", <a href="http://www.abrf.org/JBT/Articles/JBT0014/JBT0014.html">http://www.abrf.org/JBT/Articles/JBT0014/JBT0014.html</a> . Pages 1-12.			
	*Wu, et al., "A Novel Methodology for Assignment of Disulfide Bond Pairing in Proteins", <i>Protein Science</i> , 6(2): 391-398, 1997.			
	*Zhou, et al., "Assignment of Disulfide Bonds in Proteins by Partial Acid Hydrolysis and Mass Spectrometry", <i>Journal of Protein Chemistry</i> , 9(5): 523-532, 1990.			
<b>EXAMINER</b>			<b>DATE CONSIDERED</b>	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.				